

## **REMARKS**

### ***The invention***

The present invention relates to expression vectors encoding recombinant, single chain, MHC class II heterodimers that associate with an antigenic peptide and presenting the peptide to a T cell receptor. The MHC class II complexes comprise  $\alpha$  and  $\beta$  chains of the MHC class II molecule covalently linked to each other via an amino acid linker comprising the amino acid sequence as set forth in SEQ ID NO: 36. The MHC class II complexes also comprise an antigenic peptide covalently linked to the MHC class II heterodimer portion of the complex via an amino acid linker of 5 to 25 amino acids. In these complexes, the antigenic peptide binds to the antigen binding pocket of the MHC class II component and is specifically recognized by the target T-cell. These single-chain MHC II:peptide complexes can be used, *e.g.*, to treat autoimmune diseases.

### ***Status of the Claims***

Claims 39, 41-42, 44-46 and 50-54 are pending. Claims 39, 41, 42, 44-46, and 50-54 are rejected under 35 U.S.C. § 112, first paragraph.

### ***Rejections Under 35 U.S.C. § 112, first paragraph***

Claims 39, 41, 42, 44-46, and 50-54 are rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description for the recitation “ $\beta 1\beta 2$  domain” in the claims or specification as originally filed. Applicants respectfully traverse this rejection.

As set forth in MPEP § 2163(I)(B), “newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

Applicants respectfully assert that there is ample express disclosure in the specification for the recitation “ $\beta 1\beta 2$  domain.” As set forth in the specification at page 14, lines 5-21, the present invention provides soluble, fused MHC class II complexes comprising  $\alpha$  and  $\beta$  chains of the MHC class II molecule covalently linked to each other via an amino acid linker. The specification at page 14, line 22 to page 15, line 25, describes the soluble, fused MHC

heterodimer:peptide complexes as comprising a first DNA segment encoding at least a portion of a first MHC molecule (*e.g.*, a  $\beta 1\beta 2$  domain). In particular, the specification at page 14, lines 12-18 explicitly states that the first DNA segment may contain a  $\beta$  chain of an MHC class II molecule; and the specification at page 14, lines 20-21 explicitly states that the  $\beta$  chain can include the  $\beta 1\beta 2$  domain of the MHC class II molecule. In addition, the specification at page 8, line 32 to page 9, line 12, defines domains of MHC molecules and explicitly states that the domains include  $\beta 1$  and  $\beta 2$  in tandem (*i.e.*,  $\beta 1\beta 2$ ) (*see, e.g.*, page 9, lines 11-12). Thus, there is express disclosure in the specification to support the recitation “ $\beta 1\beta 2$  domain” in the claims.

In making this rejection, the Examiner also refers to the specification at page 7, lines 4-12 and alleges that to support the recitation in claim 39 of “a first nucleic acid segment encoding a first polypeptide segment comprising a  $\beta 1\beta 2$  domain of an MHC class II molecule,” there must be a disclosure in the specification that a first DNA segment be bound in order to a fourth DNA segment. As explained above, there is ample express disclosure in the specification for the recitation “ $\beta 1\beta 2$  domain of an MHC class II molecule.” Applicants respectfully note that the specification at page 7, lines 4-12 describes a specific embodiment of the invention which comprises a fourth DNA segment.

A perusal of claim 39 reveals that there is no limitation in the claim referring to a fourth DNA segment. More particularly, claim 39 recites, *inter alia*, “a first nucleic acid segment,” a second nucleic acid segment, and a third nucleic acid segment.” The first nucleic acid segment is connected in frame to the second nucleic acid segment. The third nucleic acid segment is connected in frame to the fusion of the first DNA segment and the second DNA segment. Thus, claim 39 contains no recitation referring to a fourth nucleic acid segment. The specification at page 14, lines 22-34 provides express disclosure of the soluble fused MHC heterodimer:peptide complexes comprising a first nucleic acid segment connected in frame to a second nucleic acid segment and a third nucleic acid segment connected in frame to the fusion between the first nucleic acid segment and the second nucleic acid segment. Therefore, there is ample express disclosure in the specification for each of the recitations of claim 39, including the recitation “ $\beta 1\beta 2$  domain.”

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Amdt. dated February 25, 2004  
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Examining Group

PATENT

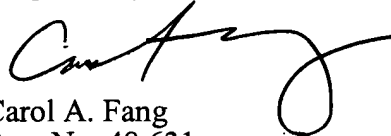
In view of the foregoing remarks, Applicants respectfully submit that there is ample disclosure in the specification for the recitation "β1β2 domain" in claim 39 and request withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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